



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-304/CMS-304a, CMS-368/CMS-R-144 and CMS-10517]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by **IOFR—INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER**:

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and

recommendations must be received by the OMB desk officer via one of the following transmissions:

OMB, Office of Information and Regulatory Affairs

Attention: CMS Desk Officer

Fax Number: (202) 395-5806 OR

E-mail: OIRA_submission@omb.eop.gov

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web Site address at

<http://www.cms.hhs.gov/PaperworkReductionActof1995>.

2. E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786-1326.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term “collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an

existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Reconciliation of State Invoice and Prior Quarter Adjustment Statement; Use: Form CMS-304 (Reconciliation of State Invoice) is used by manufacturers to respond to the state's rebate invoice for current quarter utilization. Form CMS-304a (Prior Quarter Adjustment Statement) is required only in those instances where a change to the original rebate data submittal is necessary. Form Number: CMS-304 and -304a (OMB control number: 0938-0676); Frequency: Quarterly; Affected Public: Private sector - Business or other for-profits; Number of Respondents: 1,037; Total Annual Responses: 4,148; Total Annual Hours: 187,880. (For policy questions regarding this collection contact Andrea Wellington at 410-786-3490.)

2. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Medicaid Drug Rebate Program Forms; Use: We develop the rebate amount per drug unit from information supplied by the drug manufacturers and distributes these data to the states. States then must report quarterly to the drug manufacturers and report to us the total number of units of each dosage form/strength of their covered outpatient drugs reimbursed during a quarter and the rebate amount to be refunded. This report is due within 60 days of the end of each calendar quarter. The information in the report is based on claims paid by the state Medicaid agency during a calendar quarter. Form CMS-R-144 (Quarterly Report Data) is required from states quarterly to report utilization for any drugs paid for during that

quarter. Form CMS-368 (Administrative Data) is required only in those instances where a change to the original data submittal is necessary.

Form Number: CMS-368 and -R-144 (OMB control number: 0938-0582); Frequency: Quarterly; Affected Public: State, Local, or Tribal Governments; Number of Respondents: 56; Total Annual Responses: 224; Total Annual Hours: 12,101. (For policy questions regarding this collection contact Andrea Wellington at 410-786-3490.)

3. Type of Information Collection Request: New collection (Request for a new control number); Title of Information Collection: The Predictive Learning Analytics Tracking Outcome (PLATO™); Use: The Predictive Learning Analytics Tracking Outcome (PLATO™) is a web-based application tool that will serve as the centerpiece of the advanced analytics initiative with the Centers for Medicare & Medicaid Services (CMS) and Health Integrity, LLC, the National Benefit Integrity Medicare Integrity Contractor (NBI MEDIC). Developed by Health Integrity, LLC and licensed for one of its contracts—the NBI MEDIC—PLATO™ utilizes a cutting-edge advanced analytics fraud detection process in conjunction with a state-of-the-art web-based user interface tool to present fraud and abuse lead information visually to Medicare Part D plan sponsors. Summary data, based on National Prescription Drug Event Data and actions from all Part D plan sponsors, is shared with law enforcement, CMS, NBI MEDIC, and Part D plan sponsors to review historic actions taken against providers who are enrolled in the Medicare Part D program, which will assist in detecting and preventing fraud, waste, and abuse. Form Number: CMS-10517 (OMB control number: 0938-New); Frequency: Monthly; Affected Public: Private sector – Business or other for-profits and Not-for-profit institutions; Number of

Respondents: 1,550; Total Annual Responses: 1,550; Total Annual Hours: 18,600. (For policy questions regarding this collection contact Delois Newkirk at 410-786-1247).

Dated: July 3, 2014.

Martique Jones,
Deputy Director, Regulations Development Group,
Office of Strategic Operations and Regulatory Affairs.

Billing Code: 4120-01-U-P

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